APPENDICES 1 & 2

Modeling the Development and Dissemination of an Emerging Medical Technology

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APPENDIX 1

MEDTECH: A Simulation Model of an Emerging New Medical Technology

Introduction

The purpose of this appendix is to present a more detailed view of the medical technology simulation model discussed in the body of the paper. This is not intended to be a comprehensive description of the computer model, MEDTECH, which contains approximately 100 active equations. Instead, the discussion will focus on only the most important relationships in the model, occasionally presenting them in equation form. We hope that this approach to model description will satisfy those who desire a "closer look" at the model.

The MEDTECH model is a deterministic system of difference equations. The equations are of three general types: level, rate, and auxiliary equations. Level (or state) equations are of the form:

$$L_t = L_{t-dt} + (dt)(R_{t-dt}),$$

where L_t is the value of the level L at time t, dt is the time interval used for computation of changes, and R_{t-dt} is the value of the rate R from time t-dt to time t. The computation interval dt is chosen to be quite small relative to other time constants in the model so that model behavior will approximate closely the continuous behavior of a corresponding system of differential equations.

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Changes in levels are produced by rate equations, which are instantaneous functions of level and/or auxiliary variables. If a level L is expressed in "units" (e.g., people), then its associated rate R is expressed in "units per time period" (people per year).

Auxiliary equations are also instantaneous functions of level and/or other auxiliary variables, and should be thought of as intermediate concepts which link levels to rates. In the MEDTECH model, these auxiliary concepts--such as the concept of "average effectiveness"--account for about half of the equations, with level and rate variables splitting the other half about evenly. Auxiliary variables help to make explicit the modeler's notions of how decision-makers in the system perceive and process the information available to them.

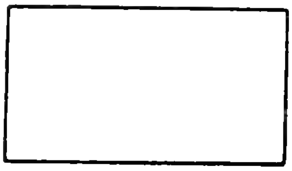
The structural relationships and parameter values in the MEDTECH model were drawn from a variety of numerical, written, and anecdotal information sources. In order to develop a general model applicable to a variety of medical technologies, we made extensive use of theoretical and empirical literature on the diffusion of innovations, particularly in the medical field. This literature was most helpful on the topic of opinion formation. Many of the relationships in MEDTECH were based on discussions with experts and other parties familiar with specific pieces of the overall system. Discussions with physicians, government policy analysts and evaluators, and company representatives involved in promotional

marketing and technical development, exposed us to a large number of issues and facts which were necessary for the construction of a comprehensive and objective model of emerging medical technologies. These discussions served as an invaluable "reality check" throughout the development of the model.

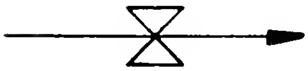
All three kinds of information mentioned above were useful in specifying the MEDTECH model to the case of PTCA. The primary source of numerical data was the PTCA registry, which contains detailed information regarding the usage and effectiveness of the procedure on a center-by-center basis. Written information included journal articles and the published proceedings from an NIH-sponsored conference on PTCA held in 1979. Anecdotal information on PTCA was obtained from NIH-associated physicians and administrators and from representatives of USCI, the leading manufacturer of PTCA equipment. A comprehensive catalog of relationships, assumptions, and data used in modeling PTCA is presently being prepared.

The MEDTECH model consists of five interconnected subsystems, which will be discussed in detail below with examples drawn from the case of PTCA. These subsystems are: Usage (U), Patient Selection Criteria (PSC), Opinion Formation (OF), Evaluation (E), and Technical Development (TD). Each subsystem makes use of information which may originate from within the subsystem, from other subsystems, or from outside the entire system. The description of each subsystem is accompanied by a subsystem diagram using symbols explained in the key below (Figure 1-[illegible]). These subsystem diagrams show, in a somewhat

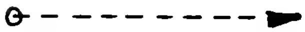
Figure 1-1. A Key to the Subsystem Diagrams



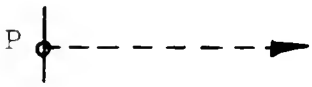
A level (state, stock, accumulation) variable



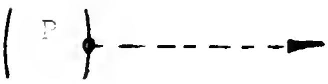
A rate (event, flow, change) variable



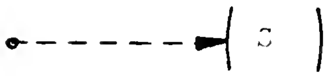
An information link



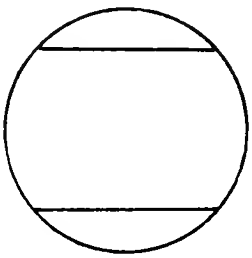
The parameter "P" is exogenous (determined outside the entire system as modeled)



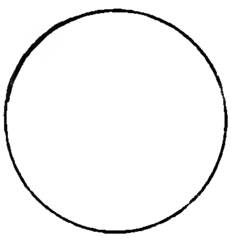
The parameter "P" is determined in another subsystem



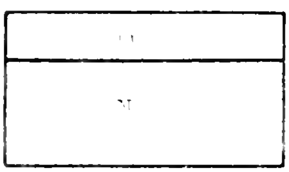
The information affects another subsystem "S"



A decision or activity function



A non-decision function



A delay or lag structure:
"T" is the delay time
"N" is the name of the delay (optional)

simplified form, the important variables and relationships in the MEDTECH model. A "decision function" consists of one or more auxiliary or level variables leading to the indicated action. A "non-decision function", by contrast, always consists of a single auxiliary variable. A delay structure consists of a series of levels and rates which produces a lag between input and output information.

Usage Subsystem (Figure 1-2)

The Usage subsystem is responsible for generating the demand and supply of procedures and their average effectiveness, as well as practitioners and their degree of expertise. Procedures are measured on a flow basis; for example, 1,000 PTCA's per year. Average effectiveness is a relative measure of the true benefit-to-cost ratio of the technique, as it is used by the average practitioner. If there were no benefits, effectiveness would equal zero. If the benefit-to-cost ratio were equal to the existing standard or goal, the effectiveness would equal 1, by definition. Thus, effectiveness will take on values greater than 1 when the standard for effectiveness is exceeded by the average practitioner. Practitioners are physicians who have the know-how, the materials and equipment, the staff, and the time required to perform procedures on a regular basis. Practitioners are assumed to have a certain maximum capacity to perform procedures (e.g., 60 procedures per year per practitioner, in the PTCA model), and a certain normal or desired utilization level of that capacity

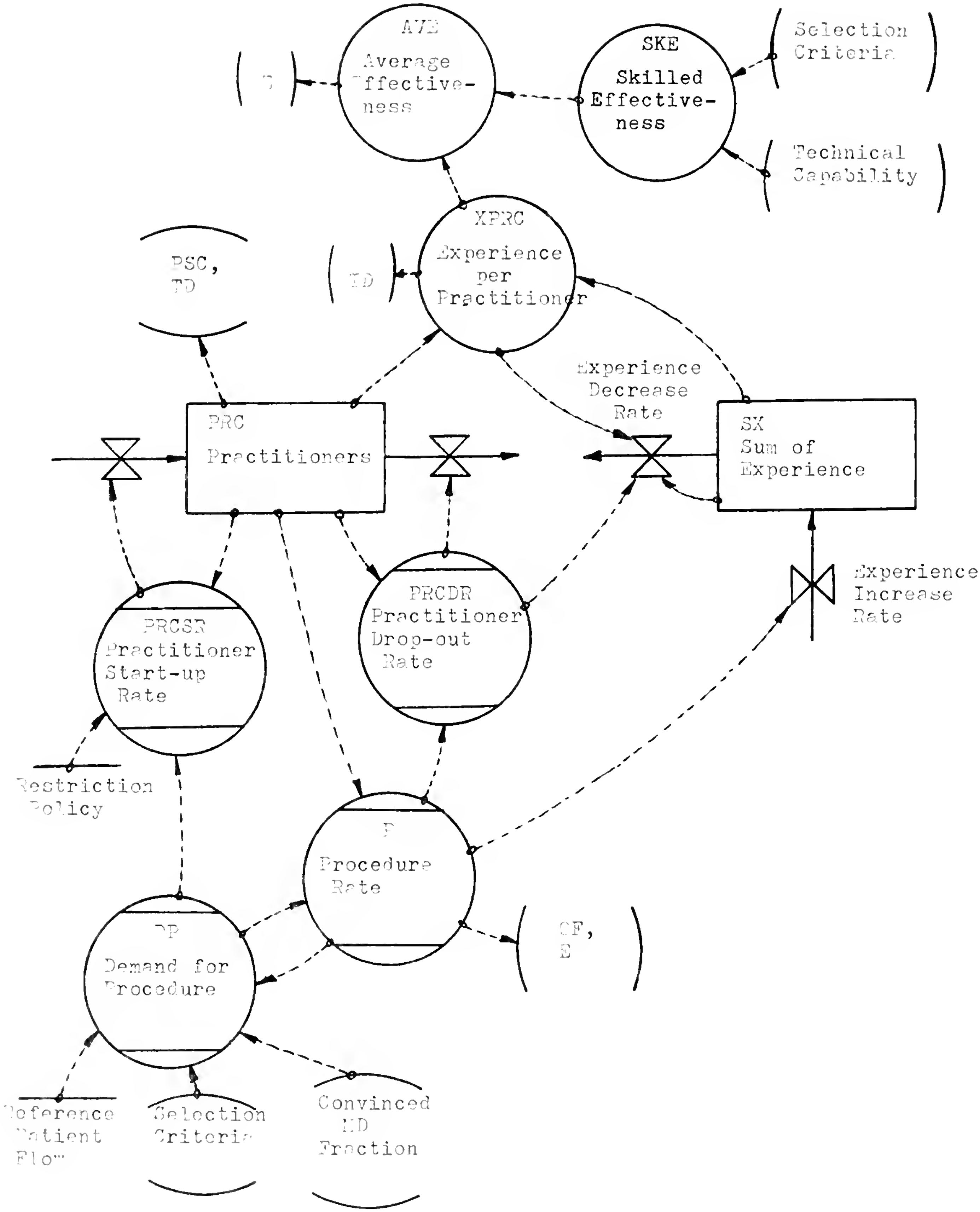


Figure 1-2. USAGE (U) SUBSYSTEM

(two-thirds, in the PTCA model). Experience is defined as the procedures performed in the past which impinge directly on a practitioner's skill.

The demand for the procedure is computed as a product of three terms determined outside the usage subsystem, adjusted by a term which reflects recent availability of the procedure. The availability factor represents the idea that if a patient has to wait for months or must fly across the country to receive the procedure, his physician will be less likely to recommend it than if no such difficulties existed. This decision, of course, depends on the availability of alternative procedures, the urgency of the patient's condition, and other factors. Assuming there is no shortage of procedures, however, the following equation for demand obtains:

Demand for procedure = (Reference patient flow)(convinced MD fraction)(selection criteria).

This equation can be understood best by way of example. For PTCA, the reference patient flow is assumed to be the 100,000 or so coronary bypass graft candidates per year from whom PTCA recipients are selected. The convinced MD fraction represents that fraction of physicians who would recommend PTCA instead of CABG to those patients who match the selection criteria. Suppose this fraction were 10%; also suppose that the selection criteria were such that PTCA was indicated for 5% of all CABG candidates. Then our equation shows that:

Demand for PTCA = (100,000 patients/year)(.10)(.05)

= 500 patients/year

An increased demand for procedures produces two responses in the model. The first is to increase the utilization of existing capacity so that more procedures can be performed with the existing practitioners. In concrete terms, this means increasing the workload of the average practitioner, resulting in longer hours worked or in the undesirable displacement of some other portion of his practice. The second response to increased demand is to bring more practitioners on-line. The "practitioner start-up rate" refers to the whole process of perceiving the demand, becoming trained, and obtaining the materials, equipment, and staff required to be a practitioner. A policy which restricts the technology primarily affects practitioner start-up, making it more difficult or less advantageous to enter practice than if the restrictions did not apply.

As procedures are performed, practitioners gain experience which can improve their effectiveness. The "sum of experience" level indicates the total amount of relevant experience over all practitioners. One way in which such experience can be lost is through a natural process of depreciation or decay over time. In other words, since a procedure done yesterday is of greater benefit to one's skill than a procedure done last year, the experience value of having done a procedure must diminish over time. This process of experience depreciation may become important during periods of low demand. The second way in which the sum of experience may decrease is by "drop-out": when a practitioner decides to quit the practice, he takes along a certain level of experience. If that level is greater

than the average experience of practitioners, then the whole field may be left worse off than before his departure.

The determination of average effectiveness requires two stages. First, we look at the effectiveness with which the technology is being applied by fully-skilled practitioners. This is assumed to be a function of the ratio of the selection criteria to the technology's present technical capability. If the selection criteria are broad relative to the technique's true capability, skilled effectiveness will be low. Relatively narrow criteria can produce higher effectiveness, but only up to a point. Criteria and capability are both expressed as fractions of the reference patient flow; in the baseline PTCA model, we assumed that criteria were initially 9%, while capability was initially 6% of CABG candidates. Technical capability is defined such that when the criteria match the capability, the resulting skilled effectiveness equals 1. The skilled effectiveness function used in the case of PTCA is shown below in Figure 1-3.

Average effectiveness can now be determined by multiplying skilled effectiveness by an experience or "learning curve" effect. The learning curve is a monotonically increasing function of the average experience per practitioner. Different technologies will have different learning curves, of course, but in general, the curve becomes essentially flat as experience increases. In the case of PTCA, for example, there appears to be a significantly greater difference in skill between a ten-procedure practitioner and a twenty-procedure practitioner than between a thirty-procedure practitioner and a forty-procedure practitioner.

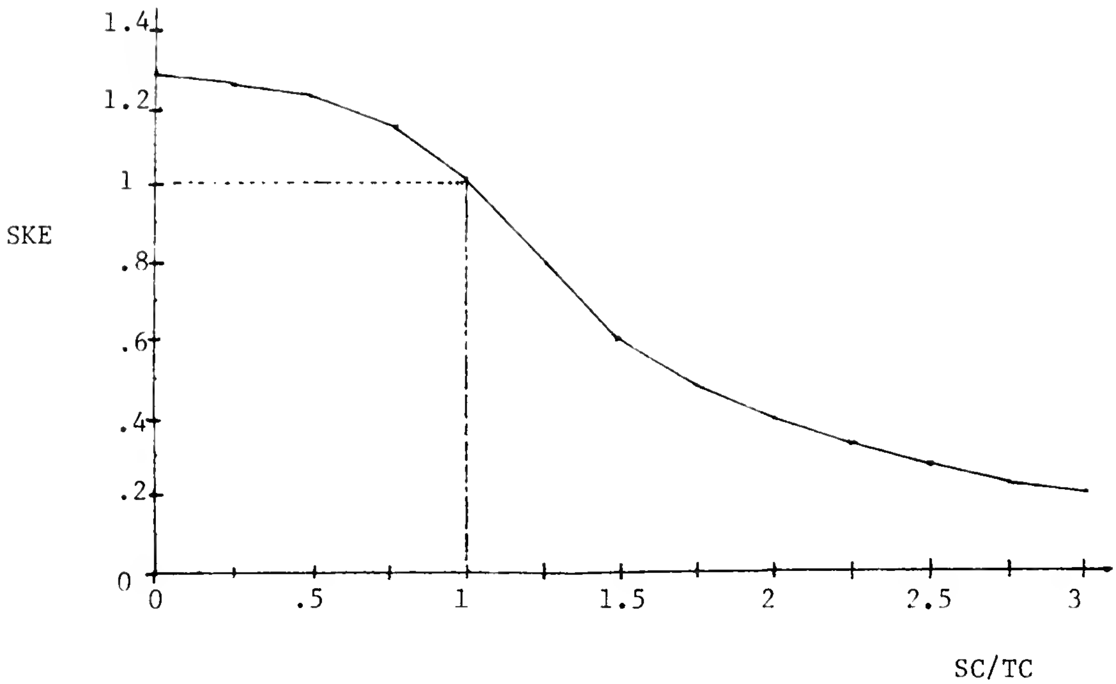
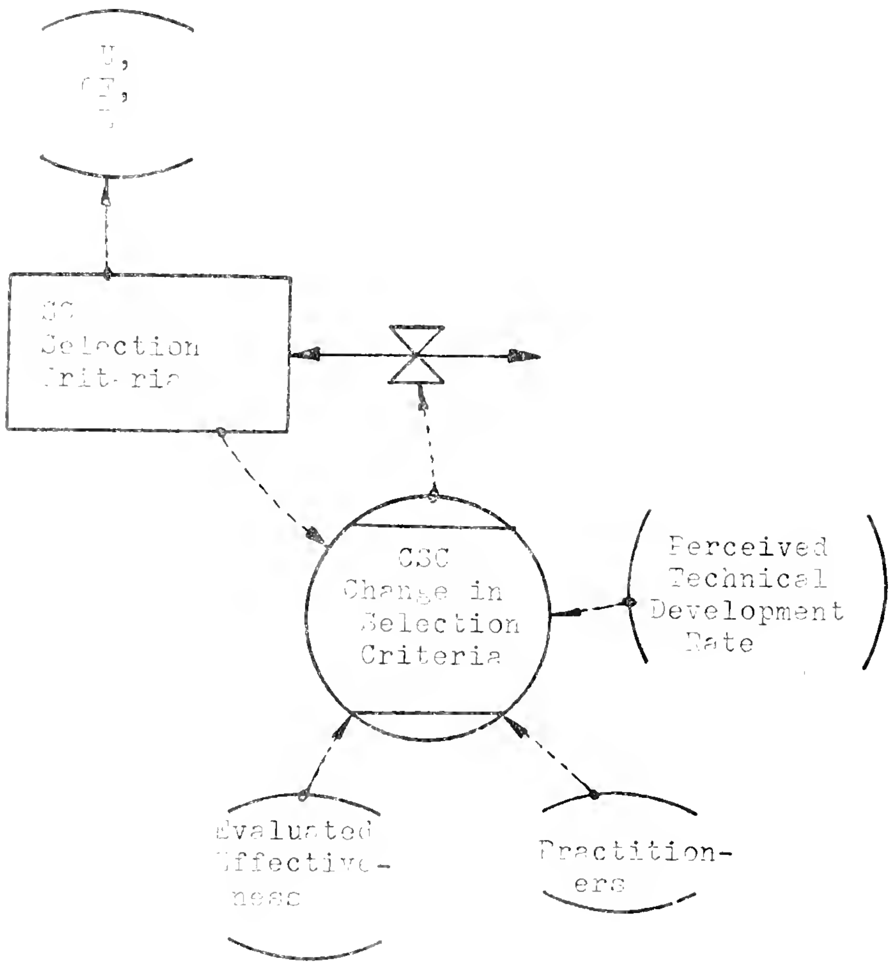


Figure 1-3. Skilled Effectiveness (SKE) as a Function of the Ratio of Selection Criteria (SC) to Technical Capability (TC).

<u>Patient Selection Criteria Subsystem (Figure 1-4)</u>

The Patient Selection Criteria subsystem generates the breadth of selection criteria, that is, the fraction of the reference patient flow considered to be candidates for the procedure. There are two factors that motivate change of the criteria. First, as practitioners adopt new technical modifications, they will tend to expand the criteria to include those patients for whom the modifications appear to make effective application possible. For instance, PTCA catheters are now being produced with new shapes that enable the practitioner to dilate lesions that were unreachable or produced problems in the past. Second, evaluations that reveal that the



ure 1-4. [illegible] SELECTION CRITERIA ([illegible]SC) SUBSYSTEM

technique's effectiveness is lower than desired will cause practitioners to become more selective in their choice of patients; that is, they will narrow the selection criteria in order to improve outcomes. Similarly, relatively high levels of evaluated effectiveness may encourage some broadening of criteria. The degree to which evaluations produce change in the selection criteria is affected by the characteristics of practitioners. When practitioners are few in number, that may imply much greater flexibility of criteria and a greater willingness to experiment with changes than when there are many practitioners. Depending on the field in question, of course, increasing numbers of practitioners may result in significantly more conservatism and less innovativeness.

The change in selection criteria originating from evaluted effectiveness is assumed to take place on a fraction-per-year basis; that is, change in criteria = (criteria)(fractional change per year). Figure 1-5 shows the relationship between evaluated effectiveness and the fractional change in selection criteria assumed in the baseline PTCA model, under conditions of maximum flexibility (relatively few practitioners).

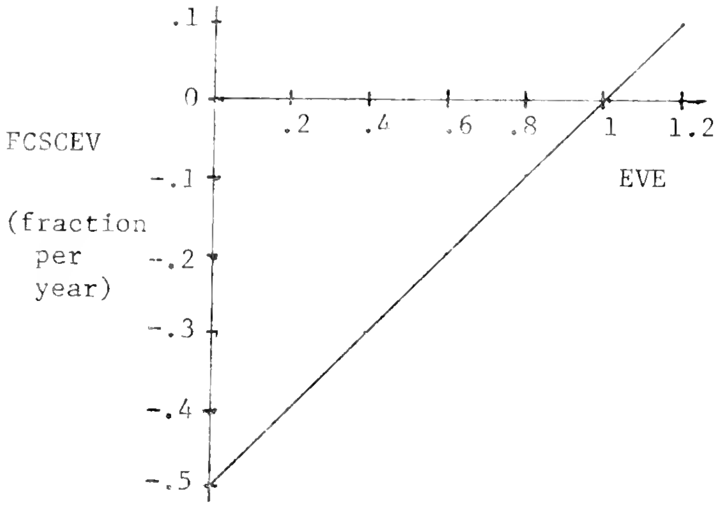


Figure 1-5. Fractional Change in Selection Criteria from Evaluation (FCSCEV) as a Function of Evaluated Effectiveness (EVE).

Opinion Formation Subsystem (Figure 1-6)

The Opinion Formation subsystem generates the Convinced MD Fraction (CMDF), which is that fraction of the physicians of reference patients who screen or consider their patients for the new procedure. Each physician is considered to be in one of three conditions: unknowledgeable (or unaware) of the technology; knowledgeable but not convinced; or knowledgeable and convinced. CMDF is the fraction of physicians in the third group. By definition, then, CMDF is equal to the product of the knowledgeable M.D. fraction (KMDF) and the convinced fraction of these knowledgeables (CFKMD); that is, CMDF = (KMDF)(CFKMD).

Awareness-knowledge may be gained from three different sources: colleague discussions, evaluative reports, and promotional marketing by manufacturers. This process of learning is seen as an

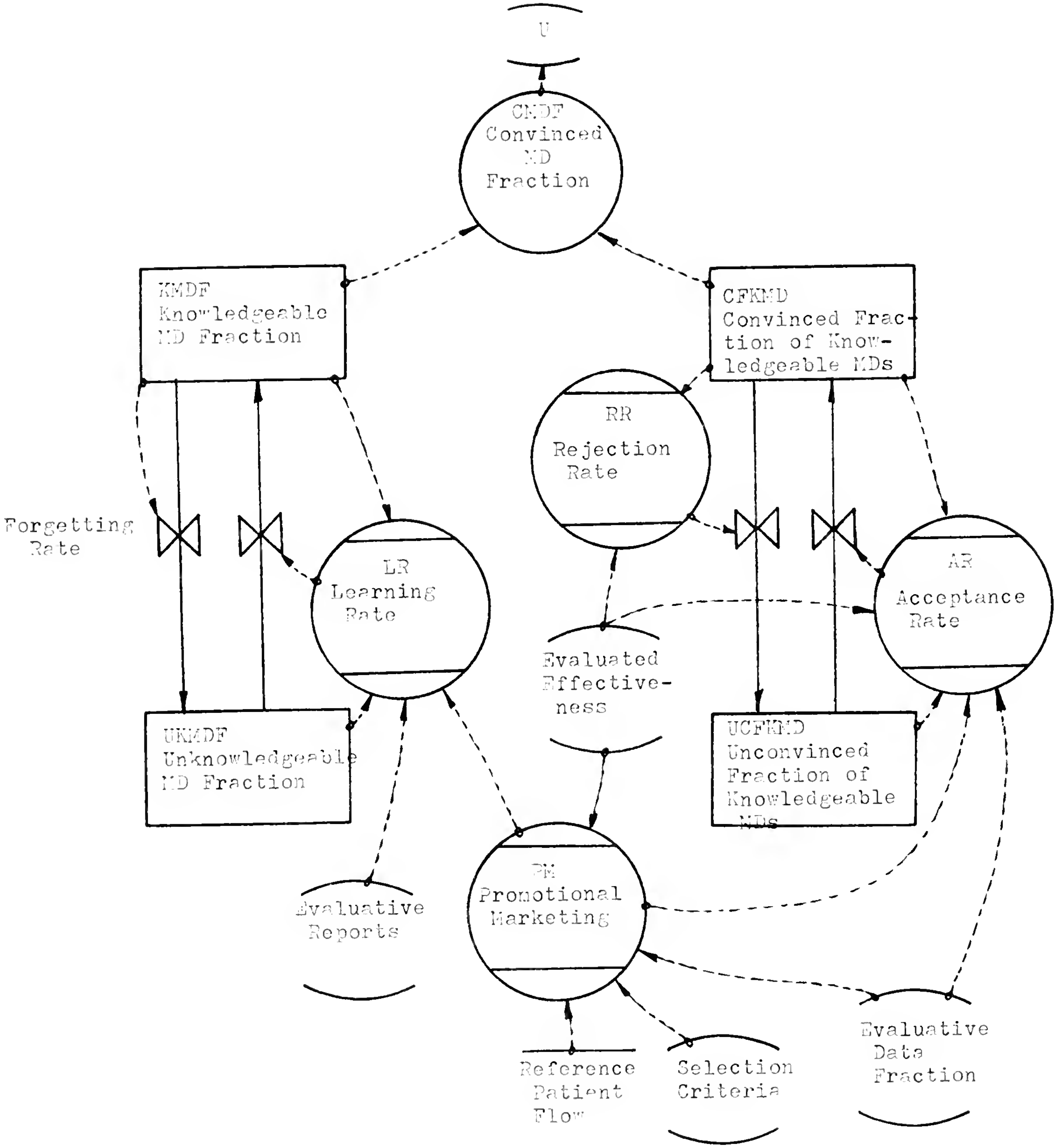


Figure 1-6. OPINION FORMATION (OF) SUBSYSTEM

active one, in contrast to the process of forgetting, which will cause awareness-knowledge to decay away naturally over time in the absence of continued learning. Colleague discussions become more likely to produce learning as the ratio of the knowledgeable to the unknowledgeable increases. Evaluative reports and promotional marketing can both perform teaching functions, but become marginally less potent as they are increased. Both professional and commercial media may encounter such "saturation" effects because of limited audiences and redundant or duplicated efforts.

The story is a similar one for the process of gaining conviction, or acceptance, which also may be based on discussions with colleagues, evaluations, and promotional marketing. In assessing evaluative data, physicians are concerned with both quantity and content: Evaluations will have their greatest persuasive effect when they both carry numerical weight and when they reveal high effectiveness. The degree to which physicians believe that the data carry weight is assumed to be related to the evaluators' own assessment of data sufficiency (the evaluative data fraction) and reflects the relative enthusiasm or confidence (versus skepticism or caution) of physicians concerning the new technology. Figure 1-7 shows the relationship between the evaluative data fraction and the "weight of evaluations for acceptance" used in the baseline PTCA model. Note that the curve lies entirely above the 45° line, demonstrating our assumption that physicians are relatively confident about the technology's ultimate value.

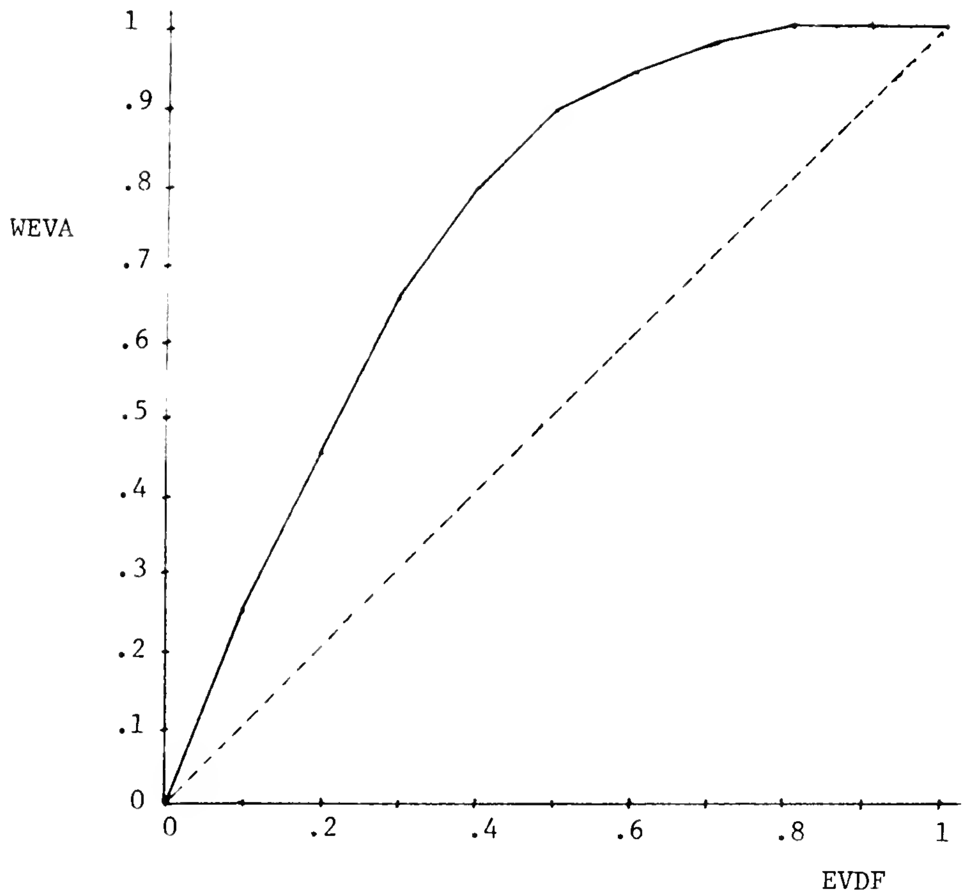


Figure 1-7. Weight of Evaluations for Acceptance (WEVA) as a Function of the Evaluative Data Fraction (EVDF).

The process of losing conviction, or rejection of the technology, is assumed to depend on evaluated effectiveness. If evaluations start to demonstrate low effectiveness, the rate of rejection may become quite high.

The decision to undertake promotional marketing is depicted in the model as a response by manufacturers to what they perceive as not enough procedures being done. Competition between manufacturers plays no role in the model, so promotion is interpreted as manufacturer efforts to increase total usage through the teaching and persua-

sion of physicians. The manufacturers' target number of procedures is assumed to be the product of the reference patient flow and the selection criteria the manufacturer believes to be supported by available evidence. Promotional marketing will tend to increase when a gap opens between this target and the actual supply of procedures.

Evaluation Subsystem (Figure 1-8)

The Evaluation subsystem generates evaluative reports and data that reflect the technology's effectiveness. A central feature of the evaluation process is the time required to collect and analyze follow-up data on patients. Obviously, the longer this evaluation completion time is, the greater the likelihood that evaluations reflect past rather than present effectiveness of a dynamic new technology.

Evaluations are undertaken in response to a gap between the goal for evaluative data and the present level of evaluative data. (The "evaluative data fraction", discussed in the previous section, is simply the ratio of evaluative data to the goal for data; both are expressed in numbers of patient-records.) However, if the number of procedures being done is small, this may constrain evaluation starts. If the problem is not with the number of procedures being done, but rather with the number being reported, a voluntary registry may serve to increase the number of cases under evaluation.

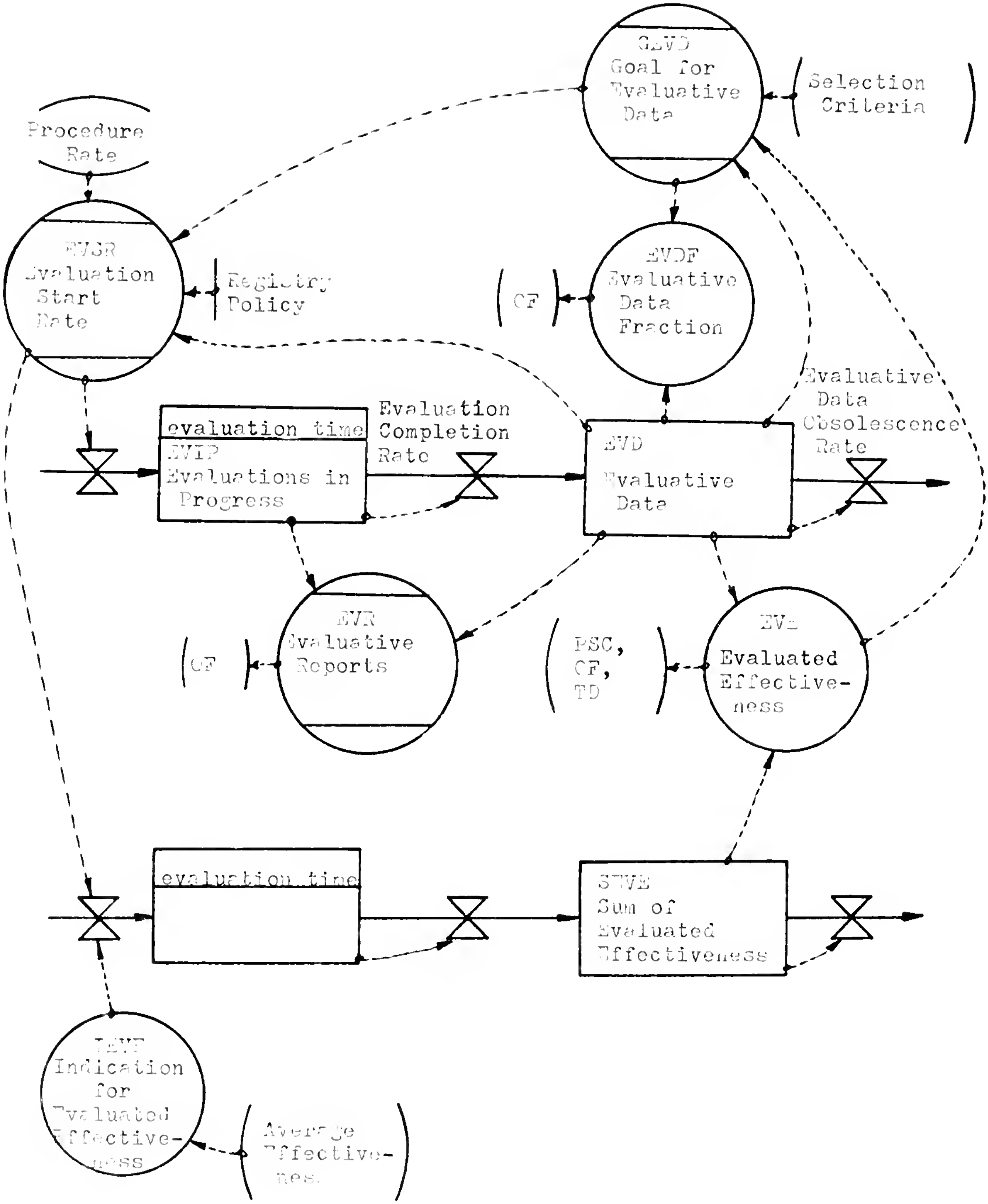


Figure 1-3. <u>EVALUATION (E) SUBSYSTEM</u>

The goal for evaluative data responds to the breadth of selection criteria and the evaluated effectiveness. As the criteria expand, there will be a greater need for data to support the practice. For example, if practitioners were to suddenly start using PTCA for a larger class of patients--say, for dilation of non-discrete atheromatous lesions--then more data would be required to substantiate the new applications. If the evaluated effectiveness is less than 1, this indicates there is a need to become more selective in the choice of patients, and consequently a need to evaluate the technique more intensively. Conversely, if the evaluated effectiveness is quite high and outcomes fairly certain, the requirement for data will be lower than when the situation is uncertain.

The frequency of evaluative reports (which affects the learning process) is assumed to be a function of both evaluations in progress and the existing quantity of evaluative data. Public statements regarding new findings occur not only because of the sheer number of such findings, but also because of their relative contribution to the existing data base. In the case of PTCA, for example, there was a flurry of reports, including a press conference, all within a couple years of the first procedure and during a time when the technique was considered experimental. In the model, this significance or novelty effect is represented as a function of the ratio of evaluations in progress to evaluative data, as shown in Figure 1-9.

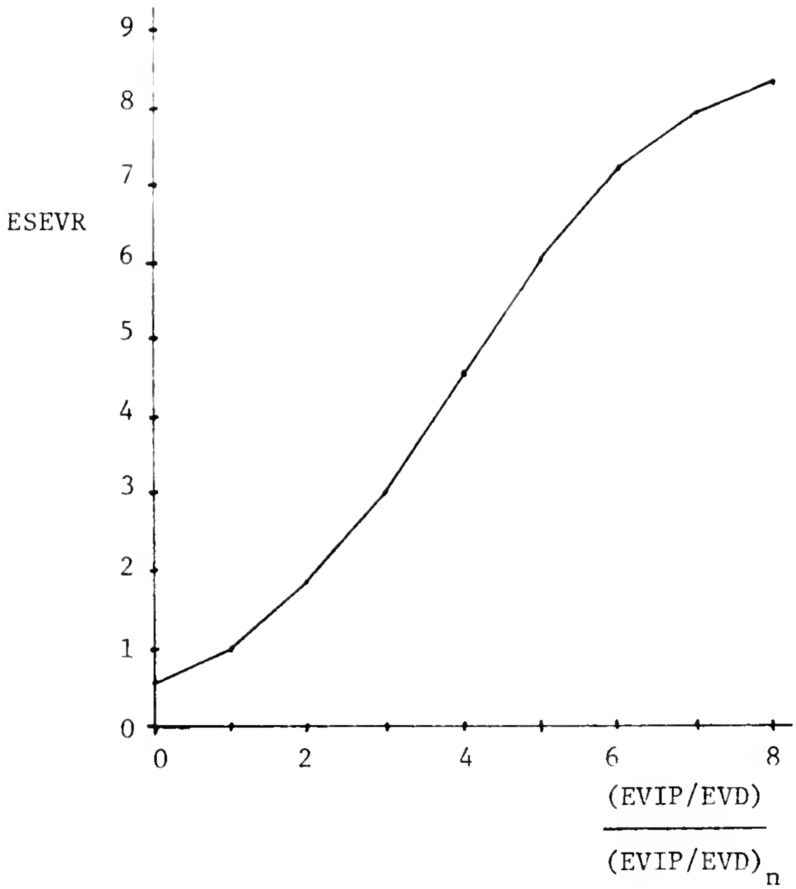


Figure 1-9. Effect of Significance on Evaluation Reports (ESEVR) as a Function of the Ratio of Evaluations in Progress (EVIP) to Evaluative Data (EVD).

(Subscript of "n" indicates normal or equilibrium value).

By definition, evaluated effectiveness is computed by dividing the sum over all evaluative data of effectiveness (SEVE) by the amount of evaluative data (EVD). Associated with each patient-record is an indication of how that record will appear after the evaluation is completed. A "perfect" evaluation technique would be one for which the Indication of Evaluated Effectiveness is exactly equal to the true effectiveness. A less comprehensive or careful analysis might err on the optimistic side, thus encouraging greater

use of the technique than is actually warranted. In fact, overuse of the technology in the long term can only occur (in the model, at least) if evaluations consistently overestimate effectiveness. This may explain much of the current interest in randomized clinical trials, which occasionally reveal problems with a technique that non-randomized evaluations miss.

Technical Development Subsystem (Figure 1-10)

The Technical Development subsystem generates modifications to the original innovation which may increase its capability for effective application. Technical modifications may be thought of as manufacturer-created, although that is not necessarily the case. Demand for modifications--that is, the set of ideas or suggestions that motivates a manufacturer's development effort--is assumed to come from practitioners, who are in the position to recognize potential improvements, based on their experience and innovativeness, evaluative data, and the success of previous modifications. The leading manufacturer of PTCA equipment estimates that at least 90% of their modifications have originated with practitioner suggestions.

Technical capability is increased by the technical development rate. Neither of these quantities can be directly measured by the medical community but must be inferred by trial-and-error and careful evaluation. The technical development rate is simply the product of technical modifications and the technical development fraction, which is the degree to which a modification

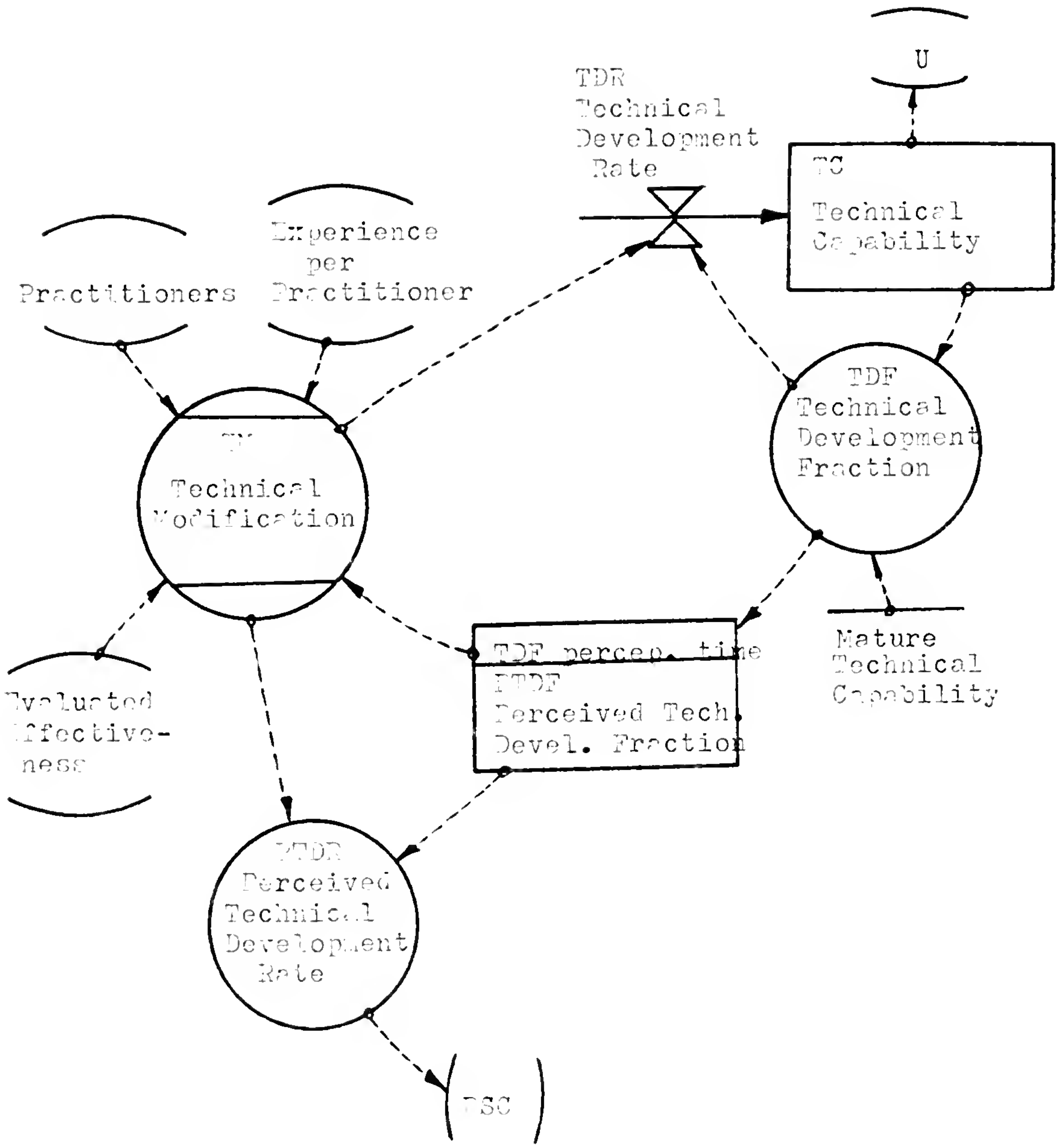


Figure 1-10. TECHNICAL DEVELOPMENT (TD) SUBSYSTEM

increases technical capability. The technical development fraction will decrease as technical capability increases. This means that there will be diminishing returns to modification as the technique matures. In the model, the technical development fraction is a function of the ratio of technical capability to "mature technical capability", a parameter which is indicative of the technology's true potential. In the baseline PTCA model, the mature technical capability was assumed to be .2, or 20% of all CABG candidates. As Figure 1-11 shows, our definition of maturity is such that when technical capability equals mature technical capability, the technical development fraction (TDF) is 1/20th of its maximum or "normal" value (TDFN). In general, TDF = (TDFN)(Effect of Technical Maturity on Development).

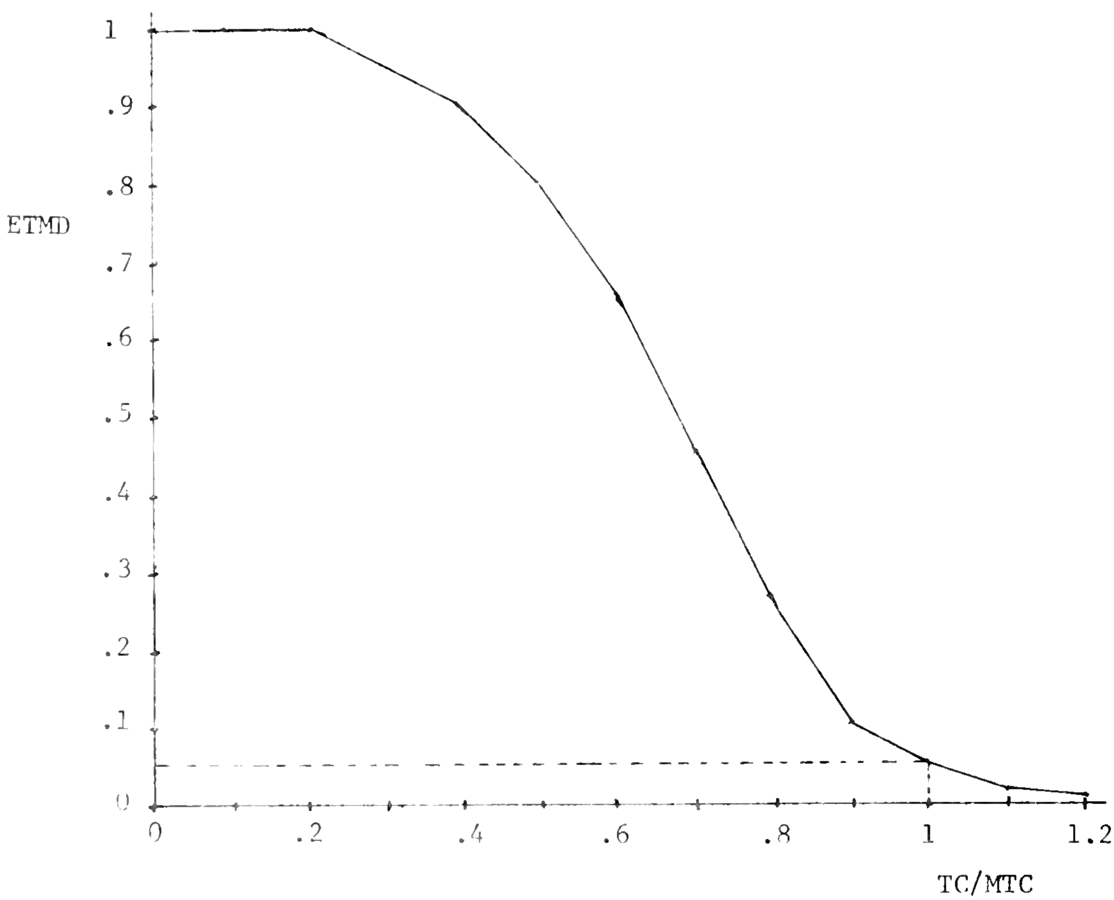


Figure 1-11. Effect of Technical Maturity on Development (ETMD) as a Function of Technical Capability (TC) relative to Mature Technical Capability (MTC).

After a period of time required to try out the new modifications, practitioners get an impression of their marginal contribution to technical capability; this is the perceived technical development fraction. Just as the true amount of development is the product of modifications and the technical development fraction, the perceived development rate is the product of modifications and the perceived technical development fraction. The lag between actual and perceived development fractions implies that practitioners may seriously overestimate the significance of new modifications, based on the success of previous ones, if the actual development fraction is declining rapidly.

APPENDIX 2

Behavior of the MEDTECH Model under Alternative Assumptions and Policies

Introduction

The purpose of this appendix is to provide a more detailed analysis of the results reported in the main body of the paper. These results consist of two parts. First, we examine more closely the behavioral elements that distinguish the "successful" pattern of usage from the "unsuccessful" pattern. Second, we display and discuss briefly the cumulative impacts of the four policy options under each of the two basic usage patterns.

"Successful" and "Unsuccessful" Patterns of Usage

The plotted output data presented here compare various aspects of the "successful" and "unsuccessful" patterns over ten years of usage, starting from the first clinical application at time 0. The "baseline" policy option of no regulations and no registry was assumed in both cases, for the purpose of easy comparison.

Figure 2-1 shows procedure demand and supply for the two cases, plotted on the same vertical scale of "procedures per year". Supply adjusts quickly to demand in both cases, because of the relatively short practitioner start-up time (1 year). Plotted alongside the "successful" usage pattern, the "unsuccessful" appears relatively insignificant. Its significance will become apparent, however, when the curves for effectiveness are examined.

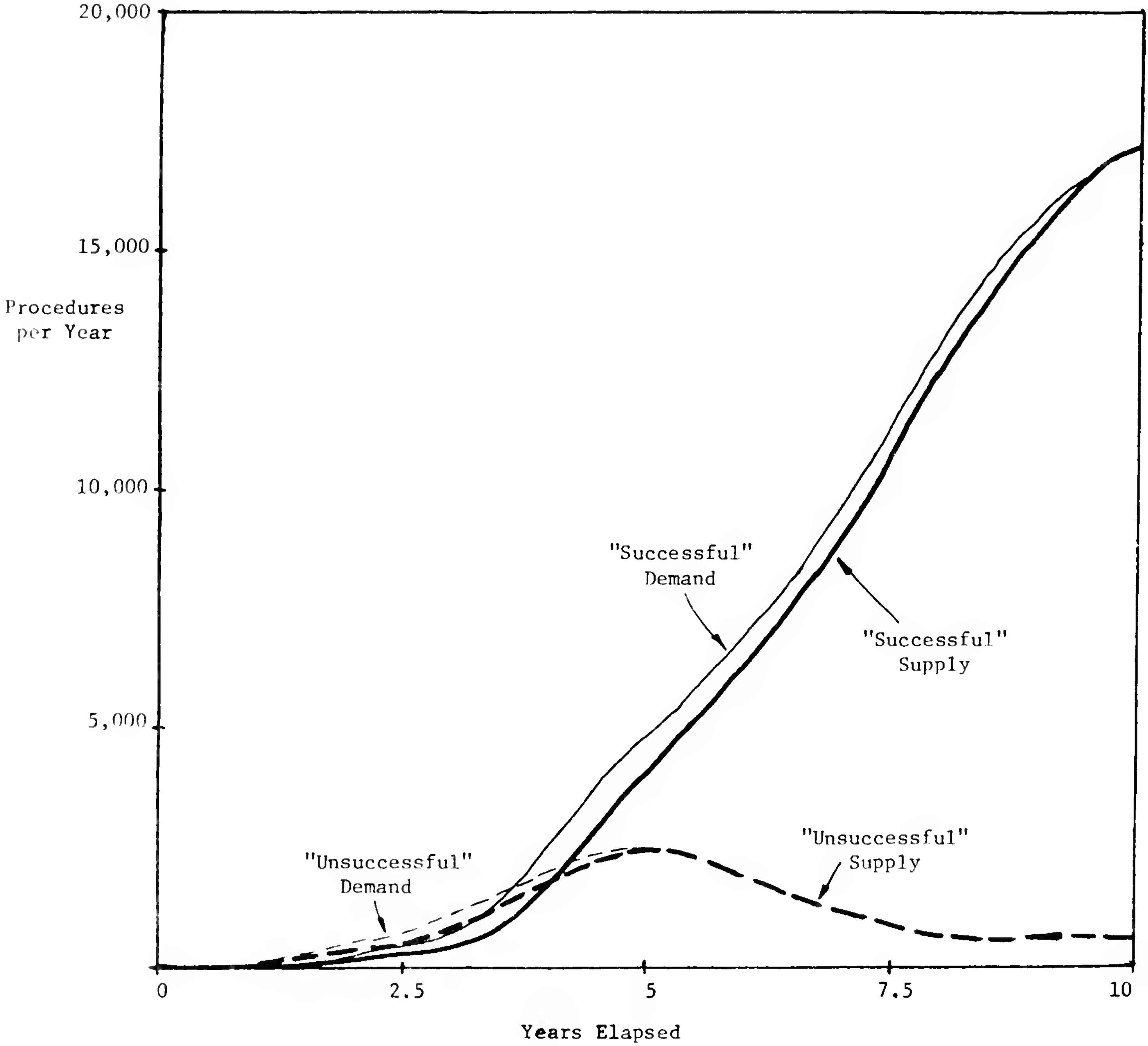


Figure 2-1. Procedure Demand and Supply under Alternative Assumptions

The primary determinants of demand for the procedure (other than the exogenous reference patient flow) are the convinced M.D. fraction and the patient selection criteria. Figure 2-2 shows the changing Convinced M.D. Fraction (CMDF) for the two cases. In the "successful" case, CMDF rises quickly and exceeds 90% by year 5. The rapid growth in knowledge and conviction seen here is triggered primarily by a burst of evaluative activity producing favorable evidence after an average follow-up time of only two years. In the "unsuccessful" case, CMDF reaches a peak of less than 40% in year 5 and then drops off smoothly. The initial growth in conviction is largely due to the appearance of high effectiveness in the short term. When evaluations are completed (after an average follow-up time of six years), however, the bad news of low effectiveness causes conviction to shrink immediately.

Figure 2-3 includes plots of selection criteria and technical capability for both scenarios, with a vertical scale running from 0 to 20% of the reference flow of CABG candidates. In the "successful" case, the criteria narrow for the first four years because of evaluations indicating lower-than-desired effectiveness. As evaluated effectiveness increases, there is less need to become more selective. Furthermore, the accelerating increase in technical capability fuels expansion of the selection criteria, which actually surpass the true capability by year 10. In the "unsuccessful" case, the selection criteria remain much higher than the actual technical capability for most of the simulation, because of a deceptively high initial appearance of effectiveness. As the evidence of

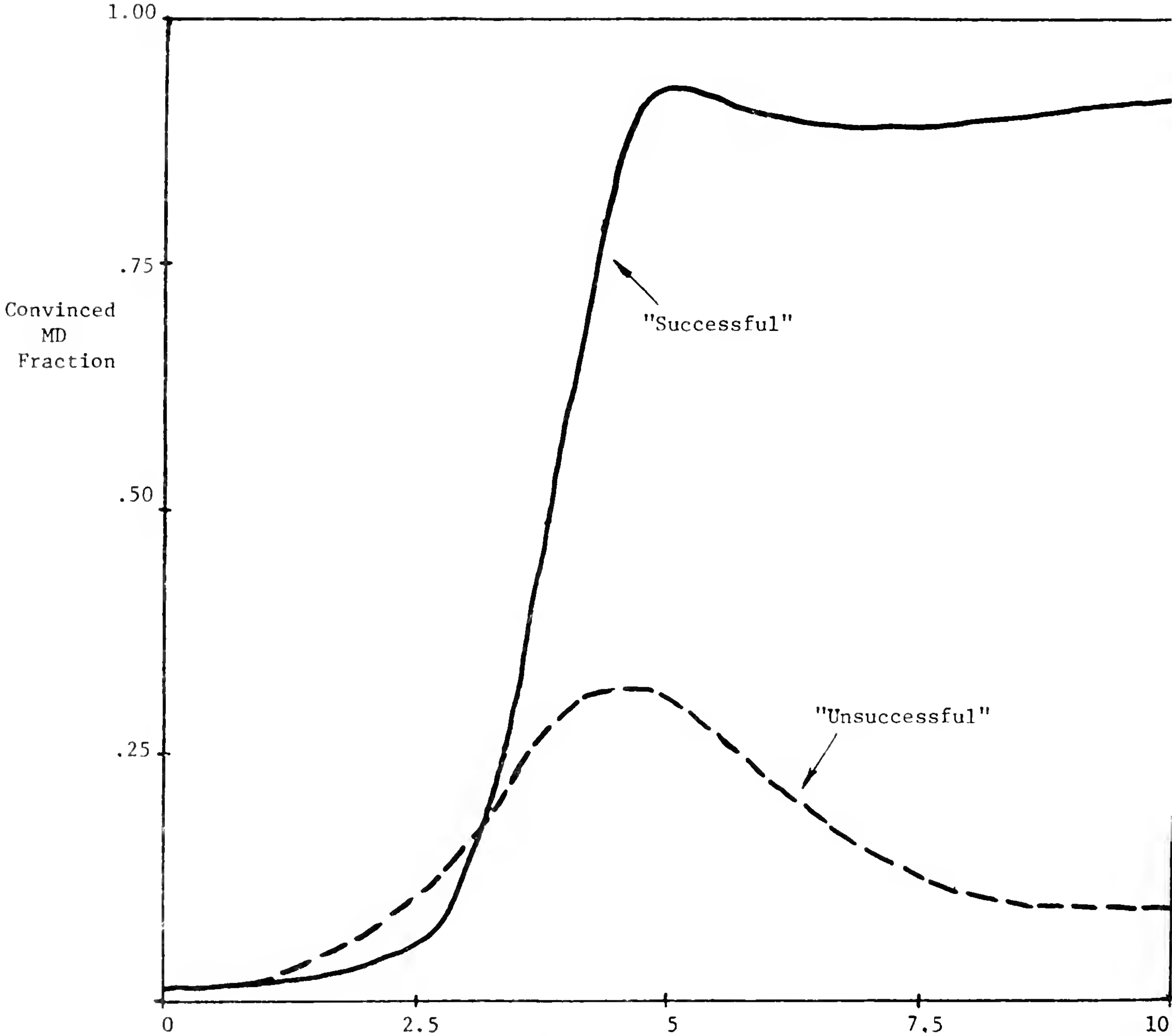


Figure 2-2. Convinced MD Fraction under Alternative Assumptions

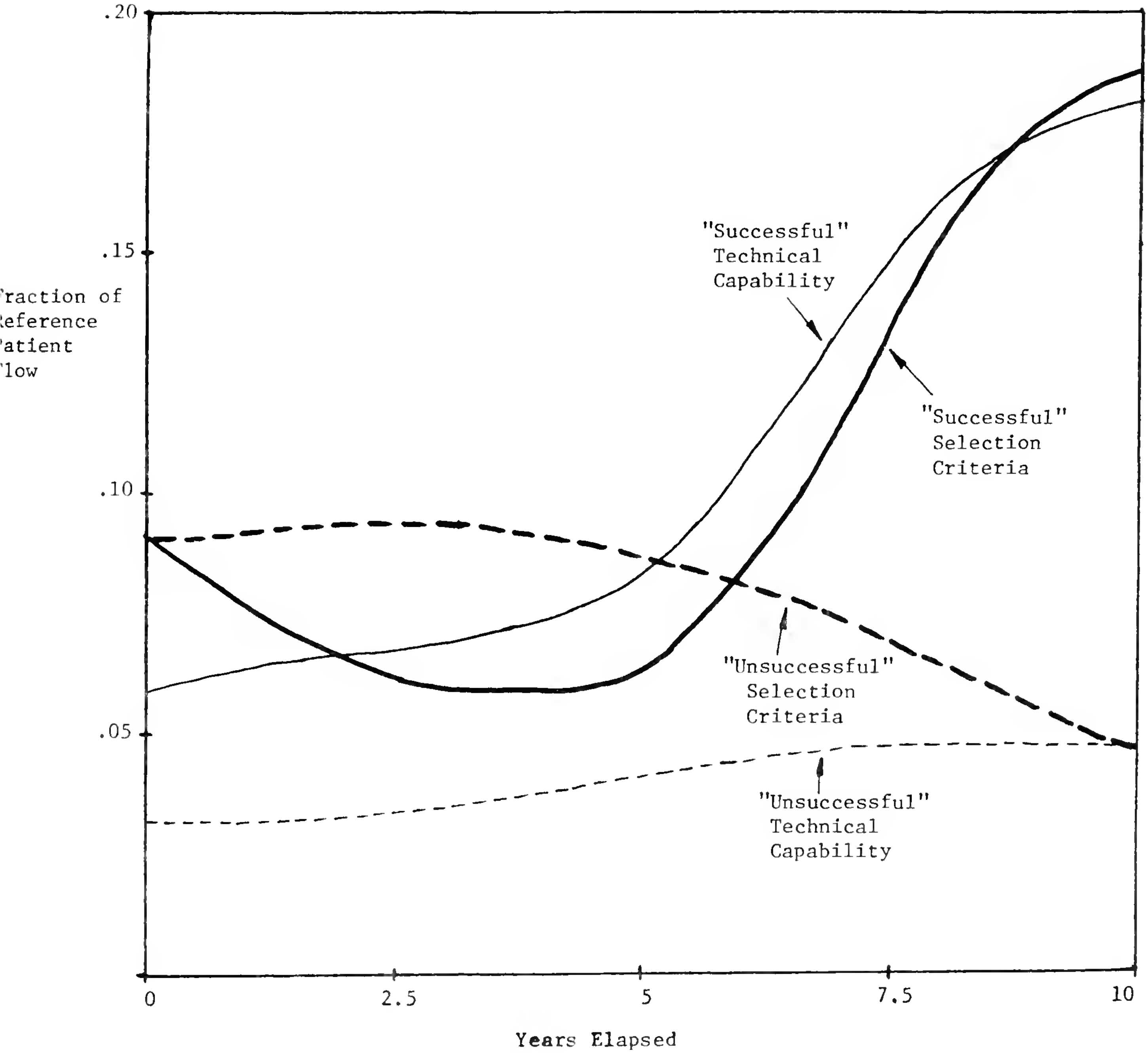


Figure 2-3. Patient Selection Criteria and Technical Capability under Alternative Assumptions

low effectiveness starts to accumulate, however, the criteria narrow and meet the true capability by year 10.

Figure 2-4 plots both average (actual) and evaluated (apparent) effectiveness for the two scenarios. In the "successful" case, average effectiveness climbs steadily for the first 2.5 years, reflecting increasing selectivity of criteria. However, as the field starts to grow and the average skill level drops, effectiveness also declines somewhat. By year 10, average effectiveness has fairly well stabilized at a high level and will continue to climb slowly toward the goal of 1.0 as practitioner experience increases and patient selection becomes even more refined. Evaluated effectiveness in the "successful" scenario is essentially a smoothed version of actual effectiveness and shows improved outcomes, especially during the first four years of narrowing criteria.

The outstanding feature in the "unsuccessful" scenario is an initial level of evaluated effectiveness which is far too optimistic. As evidence accumulates, evaluated effectiveness drops to reflect past values of actual effectiveness. Average effectiveness itself climbs from year 3 onward, because of the closing gap between selection criteria and technical capability. However, the procedure has become discredited by the end of the simulation, and it will require at least several more years for the medical community to realize that outcomes have improved significantly.

Figure 2-5 plots the effect of experience on effectiveness--the "learning curve" effect--for the two scenarios. We assume that the initial applications of the technique are performed by highly skilled practitioners who were involved in pre-clinical research and who have a good

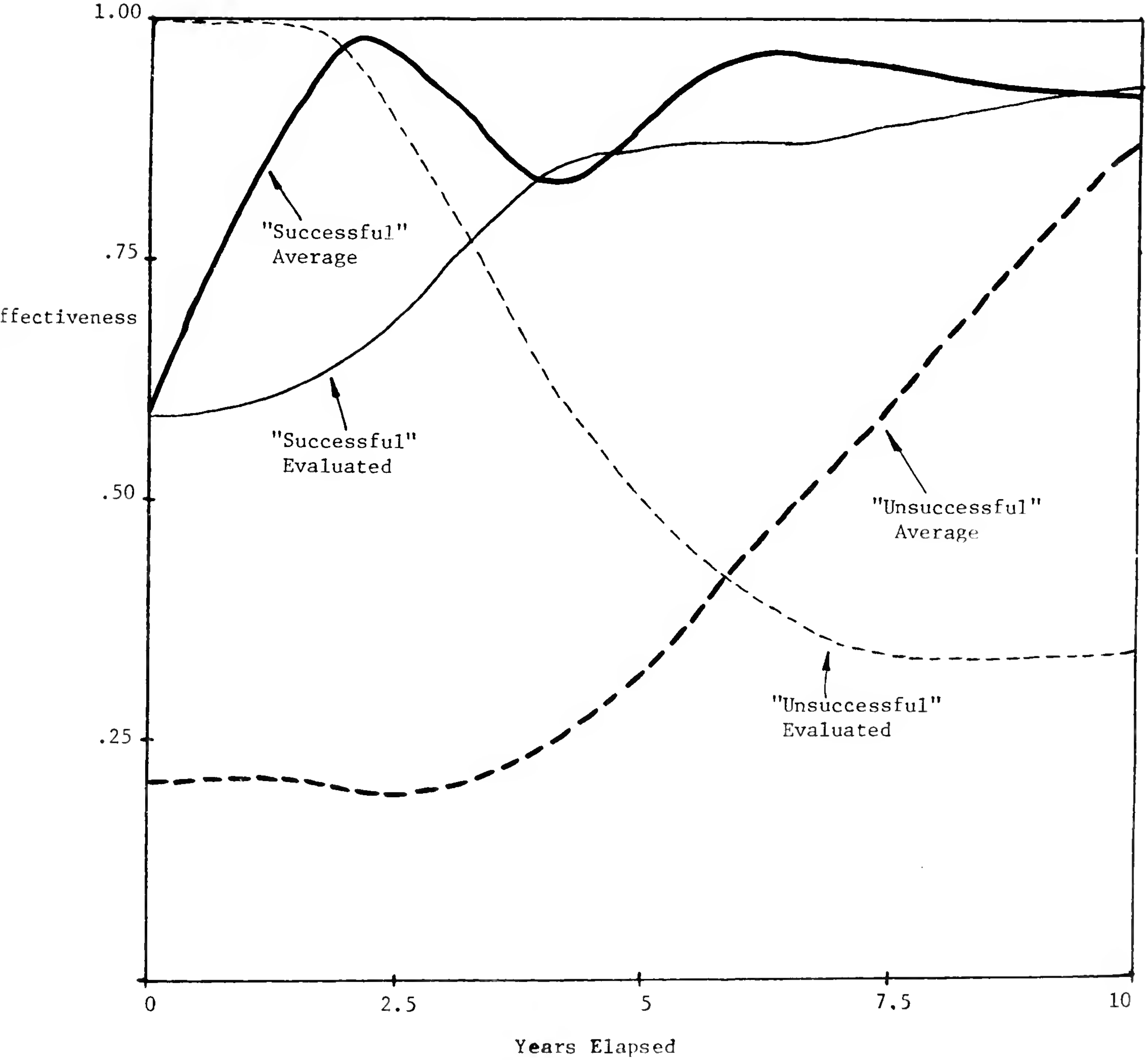


Figure 2-4. Average and Evaluated Effectiveness under Alternative Assumptions

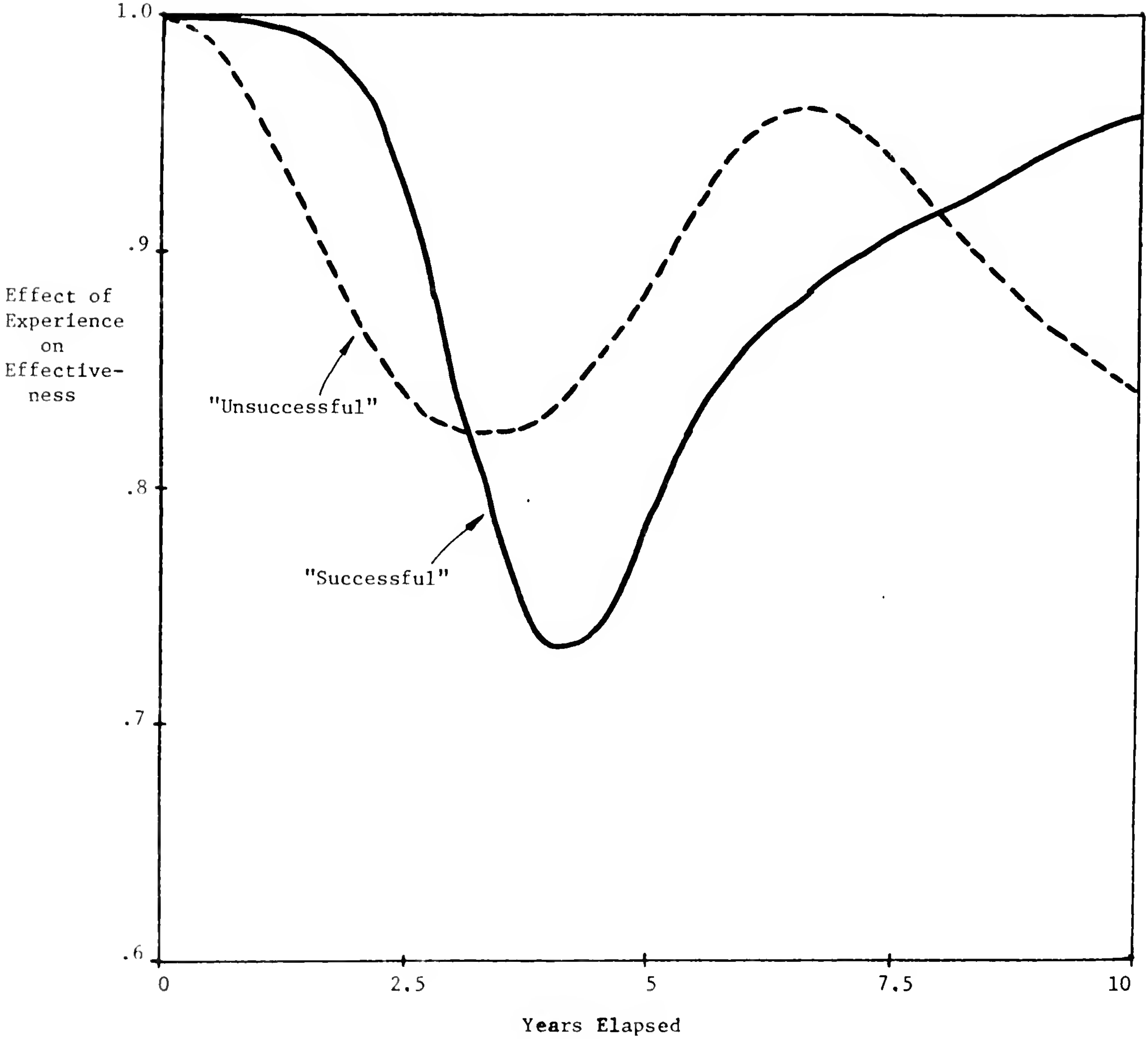


Figure 2-5. Effect of Experience on Effectiveness under Alternative Assumptions

understanding of the mechanical or chemical principles involved. The initial decline in average experience in both plots reflects the influx of inexperienced practitioners that occurs during a period of growth in demand. In the "successful" case, the trough in average practitioner experience is reached by year 4. As the growth rate declines and the pool of practitioners becomes more stable, average skill climbs back toward its initial high level. In the "unsuccessful" case, a similar decline-and-rise pattern of experience occurs but is followed by still another decline. This secondary decline is produced not by growth in demand, but rather, by lower utilization of capacity and an outflow of experienced practitioners as the practice loses popularity. Thus, there can be problems of inexperience associated both with rapid growth and rapid decline.

Cumulative Impacts of Alternative Policies

Tables 2-1 and 2-2 display the cumulative impacts of the four policy options, under the assumptions used to produce the "successful" and "unsuccessful" baseline cases, respectively. These impacts are measured along three important dimensions; namely, the quantity of procedures, their actual effectiveness, and the developed capability of the technique. "Cumulative Average Effectiveness" is simply the average over all of the procedures done to date ("Cumulative Procedures") of actual (average) effectiveness. Technical capability is by its very nature a cumulative variable and reflects the total contribution of technical modifications to date.

Table 2-1 shows clearly the delay imposed by a regulatory policy on the processes of dissemination (see "cumulative procedures") and development ("technical capability") for a "successful" technology.

VARIABLE	POLICY	Years Elapsed 5	10	20
Cumulative Procedures (in 1000's)	Baseline	3.9	56.8	233.4
	Regulation	1.4	42.1	220.8
	Registry	4.1	59.2	237.0
	Combined	1.4	43.9	223.9
Cumulative Average Effectiveness	Baseline	.86	.94	.98
	Regulation	.94	.93	.96
	Registry	.85	.93	.98
	Combined	.93	.92	.96
Technical Capability	Baseline	.082	.181	.193
	Regulation	.076	.172	.193
	Registry	.083	.181	.194
	Combined	.076	.173	.193

Table 2-1. Comparison of Alternative Policies under "Successful" Assumptions

VARIABLE	POLICY	Years Elapsed 5	10
Cumulative Procedures (in 1000's)	Baseline	4.6	10.3
	Regulation	1.2	5.1
	Registry	5.8	11.9
	Combined	1.3	5.3
Cumulative Average Effectiveness	Baseline	.24	.39
	Regulation	.26	.55
	Registry	.24	.37
	Combined	.26	.55+
Technical Capability	Baseline	.040	.047
	Regulation	.037	.044
	Registry	.041	.048
	Combined	.037	.044

Table 2-2. Comparison of Alternative Policies under "Unsuccessful" Assumptions

Initially, this delay serves to increase average effectiveness of the procedure by limiting its use to more skilled practitioners. However, as the restrictions are lifted, the supply of practitioners increases quickly and experience declines, compensating fully for the initial gains in effectiveness. Regulatory restrictions, in this case, delay not only adoption of the practice but also the establishment of stable criteria that are appropriate to the practice's true potential. However, these effects appear to be relatively small in magnitude and are of a transitory nature only.

For a "successful" technology, the registry policy, implemented either by itself or together with regulatory restrictions, appears to increase the number of procedures done while it decreases their effectiveness by a small margin in the short term. The registry spurs earlier use of the technique and therefore slightly more rapid development, but with lower average practitioner experience. The magnitudes of change are even smaller than for the regulatory policy, probably an indication that the dynamics of supply and demand (affected by regulation) are more important than those of evaluation (affected by the registry), in the case of a "successful" technology.

Table 2-2 demonstrates the ability of the regulatory mechanism to decrease usage and increase effectiveness, in the case of an "unsuccessful" technology. The beneficial effect of the restrictions appears to be greatest in the second half of the simulation (years 5-10), since the detrimental effects of quickly falling demand on average practitioner experience (see previous subsection) are largely avoided.

As in the "successful" scenario, a voluntary registry for an "unsuccessful" technology may have the effect of boosting usage by generating greater knowledge and interest among physicians. When this policy is implemented without accompanying regulatory restrictions, the result is a steeper decline in the practice after year 5 and so lower experience and effectiveness during the latter half of the simulation. However, when the registry is used in combination with restrictions, the problem of early overuse does not occur and effectiveness appears to be unaffected or possibly improved (see the "+" sign in Table 2-2). Once again, the impact of the registry under our assumptions turns out to be quite small in magnitude, rendering our conclusions relative to this policy ambiguous at best.